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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,759	03/05/2002	Adnan M. M. Mjalli	41305/271123	6863

7590

07/19/2006

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EXAMINER

PUTTLITZ, KARL J

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,759

Applicant(s)

MJALLI ET AL.

Examiner

Karl J. Puttlitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11-61 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7 and 11-61 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/28/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/2005 has been entered.

Full faith and credit is given to examination heretofore.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejected claims refer to compounds of claim 62, which is not present in the PTO's copy of those claims submitted on 4/28/2005.

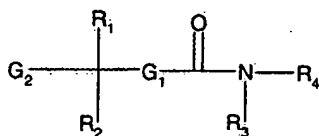
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,613,801 to Mjalli et al. (Mjalli).

The claims of the application are drawn to compounds of general formula



(I)

See definitions in claim 1.

The claims also cover sub-geni of this general formula, species, compositions and methods of treatment using the claimed compounds.

Mjalli teaches compounds of the claimed formula, see compounds described at columns 3-6.

The patent teaches treatment of RAGE-mediated diseases, see column 33.

The patent teaches compositions comprising the disclosed compounds, see column 30+.

The difference between the compounds, compositions and methods described by Mjalli and those claimed by the captioned application is that Mjalli does not teach the

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compounds with particularity so as to amount to anticipation since the patent does not teach the identical compounds as that instantly claimed. However, based on the compounds generically described in Mjalli and those specifically taught in the examples and in Table 1 at columns 6 and 7, Mjalli teaches the compounds, compositions and methods of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill.

Claims 1-7 and 11-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 7,067,554 to Mjalli et al. (Mjalli II).

Mjalli II teaches compounds of the claimed formula, see compounds described at columns 3-6.

Mjalli II teaches treatment of RAGE-mediated diseases, see column 33.

Mjalli II teaches compositions comprising the disclosed compounds, see column 32+.

The difference between the compounds, compositions and methods described by Mjalli II and those claimed by the captioned application is that Mjalli II does not teach the compounds with particularity so as to amount to anticipation since the patent does not teach the identical compounds as that instantly claimed. However, based on the compounds generically described in Mjalli II and those specifically taught in the examples and in Table 1 at columns 6 and 7, Mjalli II teaches the compounds, compositions and methods of the claimed invention with sufficient guidance,

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particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 11-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of Mjalli. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Specifically, Mjalli claims compounds of the instantly claimed generic formula.

The specific compounds claimed by Mjalli, along with the claimed generic formula, teach the instantly claimed species with the requisite particularity.

The patent claims treatment of RAGE-mediated diseases.

The patent claims compositions comprising the disclosed compounds.

Accordingly, based on the compounds generically and specifically claimed in Mjalli, Mjalli claims the compounds, compositions and methods of the instant invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill.

Claims 1-7, 11-46 and 61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of Mjalli II. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Specifically, Mjalli II claims compounds of the instantly claimed generic formula.

The specific compounds claimed by Mjalli II, along with the claimed generic formula, teach the instantly claimed species with the requisite particularity.

Mjalli II claims treatment of RAGE-mediated diseases.

Mjalli II claims compositions comprising the disclosed compounds.

Accordingly, based on the compounds generically and specifically claimed in Mjalli II, Mjalli II claims the compounds, compositions and methods of the instant invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday to Friday from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at telephone number (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Karl J. Puttlitz
Assistant Examiner